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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660
7590 12/27/2007 Daniel A. Scola, Jr.			EXAMINER	
HOFFMANN &	& BARON, LLP		PATTERSON, MARC A	
6900 Jericho Turnpike Syosset, NY 11791			ART UNIT	PAPER NUMBER
			1794	
			MAIL DATE	DELIVERY MODE
	•		12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Summary	10/002,521	GIRTON ET AL.				
omoonedammary	Examiner	Art Unit				
The MAILING DATE of this communicatio	Marc A. Patterson	1794				
Period for Reply	ir appears on the cover sheet wit	n die correspondence address				
A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN  - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory is Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	IG DATE OF THIS COMMUNIC FR 1.136(a). In no event, however, may a re on. period will apply and will expire SIX (6) MON' statute, cause the application to become AB	CATION.  sply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	16 October 2007.					
2a)⊠ This action is <b>FINAL</b> . 2b)□	This action is FINAL. 2b) This action is non-final.					
3) Since this application is in condition for al	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice un	der <i>Ex parte Quayle</i> , 1935 C.D.	11, 453 O.G. 213.				
Disposition of Claims						
4) ⊠ Claim(s) 2.3,21,22,24 and 27 is/are pendidual 4a) Of the above claim(s) is/are wite 5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 2.3,21,22,24 and 27 is/are reject 7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction as	hdrawn from consideration.					
Application Papers						
9) ☐ The specification is objected to by the Exa	miner					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection t	o the drawing(s) be held in abeyan	ce. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the call. The oath or declaration is objected to by the	,	•				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-94</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	8) Paper No(s	ummary (PTO-413) )/Mail Date Iformal Patent Application 				

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### **DETAILED ACTION**

## WITHDRAWN REJECTIONS

- 1. The 35 U.S.C. 103(a) rejection of Claims 1, 3 and 22 as being unpatentable over Landi (U.S. Patent No. 5,141,522) in view of Nagasawa (U.S. Patent No. 5,723,526), of record on page 2 of the previous Action, is withdrawn.
- 2. The 35 U.S.C. 103(a) rejection of Claim 24 as being unpatentable over Chau et al (U.S. Patent No. 4,874,568), of record on page 2 of the previous Action, is withdrawn.
- 3. The 35 U.S.C. 103(a) rejection of Claim 27 as being unpatentable over Chau et al (U.S. Patent No. 4,874,568) in view of Trescony et al (U.S. Patent No. 5,607,464), of record on page 2 of the previous Action, is withdrawn.

#### **NEW REJECTIONS**

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freiburger et al (U.S. H1978 H).

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With regard to Claims 24 and 27, Freiburger et al disclose an extrudate (column 9, lines 65 – 67) comprising an interpenetrating polymer network comprising PTFE and silicone (column 10, lines 30 – 34); Freiburger et al do not disclose a PTFE that is expanded or that has a node and fibril structure; a non – expanded PTFE having no node and fibril structure is therefore disclosed by Freiburger et al; because Freiburger et al disclose an interpenetrating polymer network, Freiburger et al disclose discrete domains of the silicone distributed throughout the PTFE that are extractable from the PTFE to create pores, as stated in paragraph 0035 of the specification, therefore permitting tissue ingrowth.

Freiburger et al fail to disclose a silicone that is solid particulate. However, Freiburger et al disclose a silicone, as discussed above. It would therefore be obvious for one of ordinary skill to select a solid particulate, or liquid silicone, as solid particulate and liquid are physical states of silicone.

6. Claims 3 and 21 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freiburger et al (U.S. H1978 H) in view of Randall et al (U.S. Patent No. 6,190,590).

Freiburger et al disclose a PTFE extrudate as discussed above. With regard to Claims 3 and 21, Freiburger et al fail to disclose a vascular graft.

Randall et al teach a vascular graft comprising PTFE extrudate (column 2, lines 1-3) for the purpose of obtaining a graft that is capable of forming a cuffed graft (column 2, lines 9 - 11). One of ordinary skill in the art would therefore have recognized the advantage of providing for the graft of Randall et al in Freiburger et al, which comprises PTFE, depending on the desired cuffing of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time

Applicant's invention was made to have provided for a vascular graft in Freiburger et al in order
to obtain a vascular graft having a cuffed graft as taught by Randall et al.

With regard to Claim 22, Freiburger et al fail to disclose a particle size of 5 to 100 microns. However, as stated above, it would therefore be obvious for one of ordinary skill to select a solid particulate, therefore of a desired size, as solid particulate and liquid are physical states of silicone.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freiburger et al (U.S. H1978 H) in view of Randall et al (U.S. Patent No. 6,190,590) and further in view of Chuter (U.S. Patent No. 6,293,969)

Freiburger et al and Randall et al disclose a PTFE extrudate comprising extractable polymeric material in a vascular graft as discussed above. Freiburger et al and Randall et al fail to disclose a radially distensible stent positioned axially about the extrudate.

Chuter teaches PTFE (PTFE membrane material; column 2, lines 49-53) comprised in first and second stents (first and second stent graft components; column 2, lines 45-47) with one stent positioned about the other stent (the stent components are at different levels, one below the other; column 2, lines 28-29) for the purpose of obtaining a stent which is biologically inert (column 2, lines 49-53). One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Freiburger et al and Randall et al, which comprises PTFE, depending on the desired inertness of the end product.

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It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Freiburger et al and Randall et al in order to obtain a stent which is biologically inert as taught by Chuter.

## ANSWERS TO APPLICANT'S ARGUMENTS

- 8. Applicant's arguments and amedments regarding the rejections of the previous Action have been considered and have been found to be persuasive. The rejections are therefore withdrawn. The new rejections above are directed to amended Claims 2 3, 21 22, 24 and 27.
- 9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc A. Patterson, PhD. Primary Examiner Art Unit 1772